

smaller and easier to work with than the neo-bladder construct, thus decreasing the length of surgery time. Also, if the insert is not seeded with cells, it can be handled extensively without fear of damaging cells.

[0163] In addition, the use of inserts allows the cells on the neo-bladder construct to remain in the medium and be exposed for a much shorter time. Without inserts, the neo-bladder construct is typically removed from the medium and remains exposed to the atmosphere while all of the vessels are sutured onto it. With this system, the neo-bladder construct will stay in the liquid medium until all of the suturing of the vessels to the inserts is completed.

[0164] Furthermore, the use of inserts allows the neo-bladder construct to be shipped to the surgeon as an intact sphere, quasi-sphere, hemisphere, or quasi-hemisphere, with holes, receptacles, or ports adapted to receive the tubular vessel or insert, and flaps for the vessels or inserts. In this case, the surgeon would not need to join the two halves of the neo-bladder construct together in the operating suite. In addition, since the flanged tubes are not attached to the neo-bladder construct prior to the time of implantation, they will produce no torque or strain on the construct during culture and shipping. Moreover, several inserts in a range of sizes could be supplied to the surgeon to account for inter-patient variation.

Flanged Tube Inserts with Washers

[0165] The neo-organ scaffolds and constructs described in this embodiment use preformed insets, holes, receptacles, or ports, adapted to receive a tubular vessel or insert, to which the tubular vessels or inserts are attached prior to implantation of the neo-organ scaffold or construct, which will take place after the neo-bladder construct is set into place. This insert has a flange at the end closest to the neo-bladder scaffold or construct and a washer (FIG. 22). The washer can be any shape or size that is suitable for the site of implantation. The washer can be made from any material suitable for use at the site of implantation. The vessel is run through the insert, which has a washer positioned on the insert tube proximal to the flange. The forward end of the vessel is splayed, and sutured or glued onto the leading face of the flange. The flanged, tubular vessel construct will be inserted into the neo-bladder scaffold or construct, through a hole, receptacle, or port adapted to receive the insert, so that the neo-bladder scaffold or construct is between the flange and the washer. The flange is then brought into contact with the interior surface of the scaffold or construct wall and the washer is brought into contact with the external surface of the scaffold or construct wall, the flange and washer thus “sandwiching” the scaffold or construct wall. This sandwiched area may then be sutured to the washer, giving added strength to this joint.

Self Stabilizing Inserts for Attachment of Vessels to a Neo Organ Construct

[0166] The inserts described herein use “gaskets” of a swellable, biodegradable material (hydrogel) to firmly attach inserts into a hollow neo-organ scaffold or construct. This insert has two flanges instead of one at the end closest to the neo-organ. The dehydrated hydrogel is located between the flanges. The flanged, tubular insert construct is inserted into the neo-organ scaffold or construct, so that the scaffold or construct wall is between the two flanges. The hydrogel then swells, forming a tight seal, thereby attaching the insert to the neo-organ scaffold or construct and preventing leakage

around the insert, which, in turn, eliminates the need for suturing and shortens operating time. As depicted in FIGS. 23-25, the insert would have two flanges at one end, with the dehydrated hydrogel in between. The hydrogel could be in the form of a washer, two or more washers, a coating on one flange, or coating on both flanges. After the vessel is attached to the insert as described above, the first flange is inserted through the wall of the neo-organ scaffold or construct. With the wall between the two flanges, the hydrogel is swollen, filling the gap between the flanges and pulling them tight against the neo-organ scaffold or construct wall. This will prevent movement of the interior flange with respect to the wall, allowing for cell migration between them and tissue regeneration across the boundary. In addition, the swollen hydrogel prevents leakage through the hole in the wall around the outside of the tube. Thus, the swollen hydrogel eliminates the need for suturing the wall closed and for suturing or otherwise fixing the insert in place. Over time, as the tissue regenerates and the vessel attaches to the neo-organ construct, the hydrogel will degrade in a manner similar to the other scaffold material.

[0167] The swellable, biodegradable hydrogel could consist of a variety of materials, including, but not limited to: cellulose, starches, gelatins, collagen, chitosan, crosslinked proteins, poly(ethylene oxide) (PEO), copolymers of PEO with other biodegradable polymers, such as polyglycolic acid, polylactic acid, polylactic-co-glycolic acid, acrylates, polyesters, etc., acrylates modified to be biodegradable, interpenetrating networks and semi-interpenetrating networks. In some embodiments, the hydrogel swells simply by exposure to water of body fluid. Alternatively, or in addition, the hydrogel could swell in response to a stimulus, such as a particular ionic concentration, pH, osmolality, or temperature change. The rate at which the hydrogel swells can be controlled by means of chemical composition, current hydration state, ion concentration, and other means. The hydrogel could be contained in a non-hydro gel membrane which possesses appropriate material properties, such as strength, toughness and pliability.

Assembled Two-Part Neo-Bladder Replacement Implant with Inserts

[0168] The two part hollow neo-bladder replacement scaffold or construct shown in FIGS. 26-28 incorporates the flanged inserts, unseeded tabs and flanged rims described above, and additionally, each half is comprised of a single-piece each. The separate pieces or hemispheres may be sutured together to form a single spherical neo-organ scaffold prior to or after coating and cell seeding. The unseeded tabs are used for maneuvering the construct parts during implantation, and the unseeded flanges are used to increase the ease of securing the two halves together. Vessels are attached to the inserts prior to implantation of the scaffold or construct. Once the neo-organ scaffold or construct is secured, the vessels are ‘plugged’ into place, thus completing the neo-bladder construct in vivo.

EXAMPLE 10

Use of the Two-Part Neo-Bladder Construct in Trigone-Sparing Augmentation

[0169] The illustration shown in FIG. 29A depicts the use of an initial augmentation construct design consisting of a